Application No.: 09/991,448 Docket No.: 300622005210

# **REMARKS**

Claims 3-4, 6-7, 10-17 and 22 are currently pending in this application. Claims 1-2, 5, 8-9 and 18-20 have been cancelled without prejudice. Claims 6-7 have been amended for clarity. Claim 13 has been amended to define the polyketide.

Claim 21 has been added, support for which is found in original claims 1, 2, 5 and 8. The remainder of the claims, now depend or ultimately depend from new claim 21. Support for new claim 22 is found in claims 10-11. No new matter has been added.

## **Priority**

In order to clarify the priority claims, applicant has rewritten the cross-referencing paragraph to indicate relationships between the applications in a more readily understandable form. In a telephone conference of January 15, 2004, Examiner Kerr indicated that the filing of a petition is unnecessary but if additional paperwork indeed needs to be filed, she is kindly requested to telephone the undersigned.

## Sequence Listing

Enclosed is a copy of the filing receipt for the sequence listing filed March 15, 2002 indicating that the applicant complied with the sequence rules. Thus, this objection may be properly removed.

# Objection to the Specification

The title, specification and abstract have been amended essentially as suggested by the Examiner. With regard to paragraph 7, on page 5 of the Office action, items a) and b) were

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addressed in the Preliminary Amendment filed November 16, 2001. Thus, the objections have been addressed.

# Objection to Claims

Claim 1 has been deleted rendering this objection moot.

#### Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-4 and 6-11 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection is traversed. Claim 1, which included the phrase "P450 monooxygenase" has been deleted. Therefore it is respectfully submitted that this rejection has been rendered moot.

Claims 1-11 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection is traversed. Claim 1 has been deleted thus mooting this rejection.

Claims 6 and 7 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. This rejection is traversed. The claims have been amended without changing the scope to delete "a" to which the Examiner objected.

Claims 12-17 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. This rejection is traversed. Claim 6 has been amended to indicate the abbreviation "(DEBS)" for 6-deoxyerythronolide B synthase. Thus, claim 12, which uses this abbreviation and which ultimately depends from claim 6, is proper. Likewise, those claims dependent on claim 12 are proper.

Claims 11, 13, 15 and 17 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. This rejection is traversed. Claim 11 has been amended to make it depend from

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claim 9 and claim 13 has been amended such that 8,8a deoxyoleandolide synthase has been defined as kindly pointed out by the Examiner.

As each of the above rejections have been addressed, it is respectfully submitted that the rejections for indefiniteness may be withdrawn.

#### Claim Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-11, 13, 15, and 17 have been rejected under 35 U.S.C. § 112, first paragraph as not providing enablement for a person skilled in the art to make the invention commensurate in scope with the claims. This rejection is traversed. Claim 1 has been deleted thus mooting the rejection as to this claim. Claim 21, from which the remainder of the claims ultimately depend, has been added and includes the subject matter of claims 1, 2, 5, and 8. Claim 21 further defines that the host cell produces an erythromycin or oleandomycin polyketide. Therefore, it is respectfully submitted that this rejection does not apply to claim 21 and those claims dependent therefrom. Withdrawal is respectfully requested.

## Claim Rejections Under 35 U.S.C. § 102

Claims 1-4 and 6-17 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Betlach *et al.* (USPN 6,251,636) and under 35 U.S.C. § 102(a) as being anticipated by Shah *et al.* (Cloning, Characterization and Heterologous Expression of a Polyketide Synthase and P-450 Oxidase Involved in the Biosynthesis of the Antibiotic Oleandomycin, The Journal of Antibiotics (May, 2000) 53:502-508). These rejections are traversed. Claim 1 has been deleted and the subject matter from claim 5 has been added to claim 21. Thus, it is respectfully submitted that claim 21 and those claims dependent thereon are not anticipated and that this rejection may be properly withdrawn.

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Claim Rejections Under 35 U.S.C. § 103

Claim 5 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Betlach

et al. (USPN 6,251,636) in view of Rodriguez et al. (FEMS Microbiol. Lett. (1995) 127:117-120).

This rejection is traversed. Claim 5 has been cancelled thus rendering this rejection moot. It is

respectfully submitted that this rejection does not apply to the present claims. One distinction is

neither Betlach or Shah disclose or suggest that the OleP is not naturally expressed by the host cell

as now claimed.

In view of the above, each of the presently pending claims in this application is believed

to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to

withdraw the outstanding rejection of the claims and to pass this application to issue. If it is

determined that a telephone conference would expedite the prosecution of this application, the

Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or

other relief is required, applicant petitions for any required relief including extensions of time and

authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection

with the filing of this document to Deposit Account No. 03-1952 referencing docket no.

300622005210. However, the Commissioner is not authorized to charge the cost of the issue fee to

the Deposit Account.

Dated: January 21, 2004

Respectfully submitted,

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